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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,012	11/26/2001	Peter M. von Dyck	713072.28	1623

27128 7590 10/02/2003

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ST. LOUIS, MO 63101

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/995,012

Applicant(s)

VON DYCK ET AL.

Examiner

Kim M. Lewis

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002 and 26 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67-69 is/are allowed.
- 6) ☒ Claim(s) 38-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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## **DETAILED ACTION**

### ***Response to Amendment***

1. The preliminary amendment filed on 11/26/01 have been received and made of record in the application file wrapper. Claims 1-37 have been canceled and claims 38-69 have been added as requested.

### ***Oath/Declaration***

2. The declaration filed 2/12/02 has been received and made of record in the application file wrapper.

### ***Power of Attorney***

3. The power of attorney papers filed 2/12/02 have been received and made of record in the application file wrapper.

### ***Drawings***

4. The corrected or substitute drawings were received on 12/26/01. These drawings are approved by the examiner.

***Claim Objections***

5. Claim 39 is objected to because of the following informalities: COP should read -continent ostomy port-- so that there is no confusion as to its meaning. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 38-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, in claim 38, the applicant recites the following, "the body portion being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port", in claim 39, the applicant recites "a first level and a second level, the first level having a perimeter sized and shaped appropriately to readily fit within the perimeter of a face plate lip of a COP", in claims 43 and 47, the applicant recites "the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port" and in claim 59, the applicant recites, "the body portion being sized and shaped for placement against a user's skin beneath a face plate

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of the ostomy port. The examiner is unable to ascertain from the specification and/or the claims the size/dimensions of the body portion and the first and second levels.

The only dimensions in the specification found by the examiner are the dimensions of the shim and the aperture of the pad. Because, the other dimensions are lacking, the examiner is unable to compare the prior art paddings with the claimed invention since the examiner cannot tell whether or not the prior art paddings are sized and shaped in a manner consistent with that of the claimed instant invention.<sup>1</sup> The remaining claims are necessarily rejected as being dependent upon a rejected base claim.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 38-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-67 are indefinite in that the examiner is unable to determine the metes and bounds of the claim (see 112, first paragraph rejection).

It has been held that where the metes and bounds of the claims are indefinite, it is improper to base a rejection on speculation as to the meaning of the claim. *In re Steele*, 305 F.2d 858, 134 USPQ 292 (CCPA 1962).

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<sup>1</sup> The examiner cautions applicant to provide support for any sizes/dimensions added to the specification. Such support can be in the form of the submission of a face plate of a continent ostomy port having its dimensions outlined.

***Allowable Subject Matter***

10. Claims 67-69 allowed.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,944,683 issued to Baranowski discloses a protection pad having a central recess and first and second levels. U.S. Patent 4,219,023 issued to Galindo discloses a pad having a first level and a second level. U.S. Patent No. 3,606,886 issued to Bittner discloses a pressure relief pad have central recess in the form of an opening. U. S. Patent No. 3,301,254 issued to Schickendanz discloses a surgical pad having two levels and a central recess.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

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**Kim M. Lewis**  
**Primary Examiner**  
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kml

September 28, 2003